

Japan Patent Office (JP)

LS #6

## Public Report of Opening of the Patent

Opening No. of patent: H 8-503506

Date of Opening: April 16, 1996

| Int.Cl.       | Distinguishing mark | Adjustment No. in Office | F1 |
|---------------|---------------------|--------------------------|----|
| C 08 L 101/00 | LSY                 | 7242-4J                  |    |
| A 61 L 27/00  | D                   | 7019-4C                  |    |
| C 08 L 33/04  | LJD                 | 8619-4J                  |    |
| G 02 B 1/04   |                     | 9219-2H                  |    |
| G 02 C 7/04   |                     | 6605-2H                  |    |

Request for examination: not requested

Request for pre-examination: requested

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Application of the patent: No. H 6-512221

Date of application: Nov. 5, 1993

Translated document submission date: May 9, 1995

International application number: No. PCT/US93/10657

International disclosure number: WO94/11764

International disclosure date: May 26, 1994

Priority right claim number: 07/973,470

Priority date: Nov. 9 1992

Country of priority right: United States of America (US)

Assigned country: EP (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), AU, JP

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## Detailed Report

(Name of invention)

polymer composition, inter-ocular lens manufactured from the same

### Abstract

A new high refractive index polymer and bendable inter-ocular lens which is manufactured from the same are disclosed. In one specific example, the polymer composition of this invention contains a co-polymer that has the following components. More than half of this co-polymer is made up of a 1<sup>st</sup> component made from a 1<sup>st</sup> monomer where the refractive index of the homopolymer is at least 1.50. Preferably, it also contains a small amount of a 2<sup>nd</sup> component which is made from a 2<sup>nd</sup> monomer different from the 1<sup>st</sup> monomer. In this 2<sup>nd</sup> monomer, the glass transition temperature of the homo polymer is less than approximately 30°C, preferably less than approximately 22°C. It also contains a 3<sup>rd</sup> component made from a monomer component which can be crosslinked in an amount sufficient for restoring the inter-ocular lens manufactured from this composition to its original shape.

### Sphere of the patent application

#### (Claim 1)

Claim 1 is concerning a composition which contains the following copolymer. More than half of this co-polymer is made up of a 1<sup>st</sup> component made from a 1<sup>st</sup> monomer where the refractive index of the homopolymer is at least 1.50. Preferably, it also contains a small amount of a 2<sup>nd</sup> component which is made from a 2<sup>nd</sup> monomer different from the 1<sup>st</sup> monomer. In this 2<sup>nd</sup> monomer, the glass transition temperature of the homo polymer is less than approximately 30°C, preferably less than approximately 22°C. It also contains a 3<sup>rd</sup> component made from a monomer component which can be crosslinked in an amount sufficient for restoring the inter-ocular lens manufactured from this composition to its original shape

#### (Claim 2)

Claim 2 is concerning the composition in claim 1 where the homo polymer of the 1<sup>st</sup> monomer component has enough strength and the glass transition temperature of the homo polymer of the 2<sup>nd</sup> monomer component is less than 22°C.

#### (Claim 3)

Claim 3 is concerning the composition in claim 1 where the copolymer is optically transparent and the refractive index is at least 1.50.

#### (Claim 4)

Claim 4 is concerning the composition in claim 1 where the 1<sup>st</sup> component makes up more than half of the copolymer and the total of the 1<sup>st</sup> component and 2<sup>nd</sup> component is at least 80 wt. % of the co-polymer.

(Claim 5)

Claim 5 is concerning the composition in claim 1 where neither the 2<sup>nd</sup> monomer component nor the 3<sup>rd</sup> monomer component contains any group containing aryl.

(Claim 6)

Claim 6 is concerning the composition in claim 1 where the 1<sup>st</sup> monomer component contains at least one group containing aryl.

(Claim 7)

Claim 7 is concerning the composition in claim 1 where the co-polymer also contains a 4<sup>th</sup> component which is made from a hydrophilic monomer component that is different from the 1<sup>st</sup>, 2<sup>nd</sup>, and 3<sup>rd</sup> monomer components. The amount of this 4<sup>th</sup> component is sufficient for reducing tackiness of the co-polymer compared to a practically identical co-polymer which does not contain the 4<sup>th</sup> component.

(Claim 8)

Claim 8 is concerning the composition in claim 1 where the 1<sup>st</sup>, 2<sup>nd</sup>, and 3<sup>rd</sup> monomer components each contain at least one functional group that contains carbon-carbon unsaturation.

(Claim 9)

Claim 9 is concerning the composition in claim 1 where the 1<sup>st</sup>, 2<sup>nd</sup>, and 3<sup>rd</sup> monomer components each contain at least one functional group that contains a carbon-carbon double bond.

(Claim 10)

Claim 10 is concerning the composition in claim 1 where the 1<sup>st</sup> monomer component is selected from styrene, vinylcarbazole, vinyl naphthalene, benzyl acrylate, phenyl acrylate, naphthyl acrylate, pentabromophenyl acrylate, 2-phenoxy ethyl acrylate, 2-phenoxy ethyl methacrylate, 2,3-dibromopropyl acrylate, and mixture of these; 2<sup>nd</sup> monomer component is selected from group that consists of n-butyl acrylate, n-hexyl acrylate, 2-ethyl hexyl acrylate, 2-ethoxy ethyl acrylate, 2,3-dibromopropyl acrylate, n-1,1-dihydroperfluorobutyl acrylate, and mixtures of these.

(Claim 11)

Claim 11 is concerning a inter-ocular lens where the size has been determined and adopted so that they can be inserted into the eyes of a mammal from cutting for use. They consist of a co-polymer that contains the following components. This co-polymer contains a 1<sup>st</sup> component which is made from a 1<sup>st</sup> monomer component with a refractive index of at least 1.50, a 2<sup>nd</sup> component which is made from a 2<sup>nd</sup> monomer component different from the 1<sup>st</sup> monomer component. In this 2<sup>nd</sup> monomer component, the glass transition temperature of the homo polymer is less than 30°C, preferably less than approximately 22°C. It also contains a 3<sup>rd</sup> component made from a monomer component which can be crosslinked in an amount sufficient for restoring the inter-ocular lens manufactured from this composition to its original shape.

(Claim 12)

Claim 12 is concerning the inter-ocular lens in claim 11 where the homo polymer of the 1<sup>st</sup> monomer component has a practical degree of strength.

(Claim 13)

Claim 13 is concerning the inter-ocular lens in claim 11 where the co-polymer is optically transparent and its refractive index is at least approximately 1.50.

(Claim 14)

Claim 14 is concerning inter-ocular lens in claim 11 where the size has been determined and adopted so that they can be distorted for insertion into the eyes of mammals.

(Claim 15)

Claim 15 is concerning the inter-ocular lens in claim 10 where the size has been determined and adopted so that they can be inserted to the eyes of mammals from approximately 3 mm cutting.

(Claim 16)

Claim 16 is concerning the inter-ocular lens in claim 11 where the 1<sup>st</sup> component make up more than half of the copolymer and the total of the 1<sup>st</sup> component and 2<sup>nd</sup> component is at least approximately 80 wt. % of the co-polymer.

(Claim 17)

Claim 17 is concerning the inter-ocular lens in claim 11 where neither the 2<sup>nd</sup> monomer component nor 3<sup>rd</sup> monomer component contains any group containing aryl.

(Claim 18)

Claim 18 is concerning the inter-ocular lens in claim 11 where the co-polymer also contains 4<sup>th</sup> component which is made from a hydrophilic monomer component that is different from the 1<sup>st</sup>, 2<sup>nd</sup>, and 3<sup>rd</sup> monomer components. The amount of this 4<sup>th</sup> component is sufficient for reducing tackiness of the co-polymer compared to the practically identical co-polymer which does not contain the 4<sup>th</sup> component.

(Claim 19)

Claim 19 is concerning the inter-ocular lens in claim 11 where the 1<sup>st</sup>, 2<sup>nd</sup>, and 3<sup>rd</sup> monomer components each contain at least one functional group that contains carbon-carbon unsaturation.

(Claim 20)

Claim 20 is concerning the inter-ocular lens in claim 11 where 1<sup>st</sup>, 2<sup>nd</sup>, and 3<sup>rd</sup> monomer components each contain at least one functional group that contains a carbon-carbon double bond.

(Claim 21 )

Claim 21 is concerning the inter-ocular lens in claim 11 where the 1<sup>st</sup> monomer component is selected from styrene, vinylcarbazole, vinyl naphthalene, benzyl acrylate, phenyl acrylate, naphthyl acrylate, pentabromophenyl acrylate, 2-phenoxy ethyl acrylate, 2-phenoxy ethyl methacrylate, 2,3-dibromopropyl acrylate, and mixtures of these.

(Claim 22)

Claim 22 is concerning the inter-ocular lens in claim 11 where the 2<sup>nd</sup> monomer component is selected from a group that consists of n-butyl acrylate, n-hexyl acrylate, 2-ethyl hexyl acrylate, 2-ethoxy ethyl acrylate, 2,3-dibromopropyl acrylate, n-1,1-dihydroperfluorobutyl acrylate, and mixtures of these.

Detailed explanation of invention

polymer composition, inter-ocular lens manufactured from the same

(Background of invention)

This invention is concerning a polymer composition and a inter-ocular lens manufactured from such composition. In more detail, this invention is concerning a polymer composition which has a high refractive index and a inter-ocular lens manufactured from the same, preferably a inter-ocular lens which can be deformed.

Inter-ocular lens (IOL) have been known for a long time since right after the end of World War II. Such lens is implanted into the eyes of mammals, for example, human eyes, in order to restore the vision of patients by replacing the natural lenses that are either damaged or diseased.

IOL are manufactured from "hard" or "rigid" polymer or optical glass such as polymethyl methacrylate (refractive index: 1.48). However, a soft elastic polymer substance has often been used for the following reasons.

Soft IOL can be deformed. For example, it can be bent or rolled for insertion. Therefore, when implanted, a smaller incision than that required for a "hard" IOL with the same optical performance is required. The smaller the incision, the less trauma to the eyes of the patient, and recovery after surgery is faster. An approximately 3 mm incision is ideal, because the natural lenses are emulsified by conventional crystalline lens emulsifying techniques, and a 3mm incision is currently required for removing it. Compared to this, a typical IOL is approximately 6 mm in diameter.

The size and mechanical properties of the IOL which can be deformed play an important role. As is well known to people in this business, for successful implantation, it is necessary that a deformable IOL has sufficient structural integrity and elasticity and elongation to enabling deformation for insertion into a small incision and it must also be sufficiently small. After insertion, this lens naturally resumes its original shape, and it has to have sufficient structural strength for maintaining its shape under normal conditions of use.

In general, a thinner deformable IOL requires a smaller incision. In order to function optically as an IOL, this lens has to have a sufficient index of refraction. If the optical refractive index of the material is higher, the IOL can be thinner and still attain the same optical performance.

An IOL made of a silicone polymer substance generally has a refractive index of approximately 1.46 or less. Accordingly, it must be thicker than an IOL made of a material with a higher refractive index. Deformable IOL made of acryl materials are too hard for use at room temperature. Because of its rigidity, when the IOL is suddenly bent, it may crack. The refractive index is close to that of a silicone polymer substance and it is also tacky. This tackiness prevents it from deforming sufficiently for insertion into a very small incision and it may produce problems with handling.

U.S. patent No. 4,834,750 by Gupta discloses an IOL which has an optical body that consists of a co-polymer of ester methacrylate which forms a relatively hard homo polymer at room temperature and ester acrylate which forms a relatively soft homo polymer at room temperature. This co-polymer is crosslinked and bonded with ester diacrylate, and an acryl substance which has a non-tacky surface and  $-30^{\circ}$  to  $25^{\circ}\text{C}$  range glass transition temperature is manufactured. This patent discloses that such optical body can be deformed for inserting into the eye. However, in this patent, there is no discussion of the refractive index of the IOL. Accordingly, none of the specific monomers disclosed in this patent offer a homo polymer with a refractive index of at least approximately 1.50.

In order to produce an IOL which has good optical properties including optical transparency and a high refractive index which also can be deformed effectively for insertion into a small incision, it is useful to offer a material for the IOL which has sufficient properties.

#### (Outline of this invention)

A new polymer substance and IOL which is manufactured from such polymer substance was found by the inventors of this invention. The polymer substance of this invention is made from a combination of monomers, and it offers useful optical feature regarding optical transparency and high refractive index. It can be effectively deformed in order to insert it into a small incision, preferably approximately 3 mm or less. Preferably, it can be formed into an IOL which can be bent. In addition, the IOL of this invention regains its original shape under the conditions existing in the eyes in an adequately short period of time. The polymer substance of this invention can be manufactured using conventional monomers and also conventional techniques, for example, conventional polymerization techniques. Accordingly, implementation of this invention is very effective and easy. As a result, a polymer substance and IOL which has excellent characteristics can be acquired.

Generally, this invention is concerning a co-polymer which contains a 1<sup>st</sup> component, a 2<sup>nd</sup> component, and a 3<sup>rd</sup> component. The 1<sup>st</sup> component is made from a monomer component where its homo-polymer has at least approximately 1.50 refractive index. This refractive index is higher than that of a methyl methacrylate homo polymer. The homo polymer of the 1<sup>st</sup> monomer component is preferably a hard type. The 2<sup>nd</sup> component is made from a monomer component which is different from the monomer component of the 1<sup>st</sup> component. Its homo polymer has a glass transition temperature of approximately  $30^{\circ}\text{C}$ , preferably less than approximately  $22^{\circ}\text{C}$ . The 3<sup>rd</sup> component is made from a monomer component for crosslinking. It exists in an amount sufficient for making it easy to deform the IOL manufactured from this composition for insertion and to regain its original shape under the conditions existing in human eyes.

In another section of this invention, an IOL where its size has been determined and adopted so that it can be inserted through an approximately 3 mm incision in deformed condition. The IOL of this invention is made of the composition in this detailed report.

Concerning these abstracts and other abstracts of this invention, they are detailed explanations, examples of practice, and claims of this document. Especially, they are explained in detail referring to attached figures that have same the reference numbers for identical parts.

(Simple explanation of figures)

Figure 1 is a top view of the IOL according to this invention.

Figure 2 is a side view of the IOL of figure 1.

(Detailed explanation of the invention)

The composition of this invention contains a co-polymer which contains at least three components. The 1<sup>st</sup> component in the co polymer of this invention contains at least approximately 10, 20 wt. %, preferably more than half (at least approximately 50 wt. %) of the 1<sup>st</sup> monomer component. The refractive index of the homo polymer of the 1<sup>st</sup> monomer component is at least approximately 1.50, preferably approximately 1.52 or 1.54. The homo polymer in the 1<sup>st</sup> monomer component should be practically rigid. The 2<sup>nd</sup> component which exists in the co polymer of this invention is made from at least approximately 3, 10, or 20 wt. % of a monomer component which is different from the 1<sup>st</sup> component. The homo-polymer of the 2<sup>nd</sup> monomer component has a glass transition temperature of approximately 30°C, preferably less than approximately 22°C.

The 1<sup>st</sup> and 2<sup>nd</sup> components should make up approximately 80 wt. %, more preferably, approximately 90 wt. % of the co-polymer of this invention. The 1<sup>st</sup> and 2<sup>nd</sup> monomer components should be selected so that each of these monomer components can be chemically reacted with the other monomer component.

A 3<sup>rd</sup> component is made from a monomer component for crosslinking. It is a monomer component which can form crosslinking bonds in the co-polymer of this invention. This monomer component for crosslinking is preferably polyfunctional, and it can be chemically reacted with both the 1<sup>st</sup> and 2<sup>nd</sup> monomer components. The amount of the 3<sup>rd</sup> component of this invention is effective for making it easy to deform the IOL manufactured from this composition, for example, to regain its original shape under the conditions existing in the human eyes within a reasonable time.

Co-polymer of this invention is optically transparent, and it has a high refractive index, for example, at least approximately 1.50, preferably, at least approximately 1.52, or approximately 1.54. This combination of characteristics of the co-polymer of this invention will enable manufacturing of an IOL which has high optical performance and can be effectively deformed.

The term, "homo polymer" in this invention means a polymer which is made from practically a single monomer component. Accordingly, this homo polymer contains a main monomer component, preferably, only a single monomer component. In order to promote forming a homo polymer, as in conventional cases, it is possible to use a small amount of catalyst, initiator, etc. In addition, the homo polymer of either the 1<sup>st</sup> monomer

component and the 2<sup>nd</sup> monomer component has a molecular weight or degree of polymerization that is sufficiently high to make a useful IOL.

The homo polymer of the 1<sup>st</sup> monomer component should be a hard type. An IOL which is manufactured from such "hard" homo polymer cannot be deformed for insertion through a small incision. The rigidity of the homo polymer of the 1<sup>st</sup> monomer component makes an IOL manufactured from such homo polymer impossible to deform, and it is either destroyed or damaged by the force required to deform it enough for insertion through a small incision.

The 1<sup>st</sup> component should make up at least approximately 10, or at least 20 wt. %, more preferably more than half of the co polymer of this invention. The 1<sup>st</sup> monomer component can be selected from compounds that meet the standard in this detailed report. This monomer component has to offer a co-polymer which has increased refractive index compared to the homo polymer of the 2<sup>nd</sup> monomer component. The index of refraction of the homo polymer of 1<sup>st</sup> monomer component must be at least approximately 1.50, preferably at least approximately 1.52 or at least 1.54.

Naturally, the 1<sup>st</sup>, 2<sup>nd</sup>, and 3<sup>rd</sup> monomer components have to be suitable for use in the eyes, have to be optically transparent, and have to offer a co-polymer which is suitable for use as an IOL. In one specific useful example, none of the 1<sup>st</sup>, 2<sup>nd</sup>, and 3<sup>rd</sup> monomer components contain practically no silicone. Because of that, the acquired co-polymer is not a silicone polymer. Each monomer component for manufacturing the co-polymer of this invention contains at least one functional group which preferably contains carbon-carbon unsaturation, more preferably a carbon-carbon double bond. This monomer component can be replaced with a non-interference substitution group which will not make the co-polymer manufactured from it toxic. Such substitution group may be one or more of the following: oxygen, nitrogen, carbon, hydrogen, halogen, sulfur, phosphorus, or a mixture or combination of these.

Especially useful 1<sup>st</sup> monomer components contain styrene, vinyl carbazole, vinyl naphthalene, benzyl acrylate, phenyl acrylate, naphthyl acrylate, pentabromophenyl acrylate, 2-phenoxy ethyl acrylate, 2-phenoxy ethyl methacrylate, 2,3-dibromopropyl acrylate, and mixtures of these.

The 2<sup>nd</sup> component makes up at least approximately 2 wt. % of the co-polymer, preferably at least approximately 4 wt. %. Any appropriate 2<sup>nd</sup> monomer component which satisfies the requirements in this detailed report can be used. The homo polymer of the 2<sup>nd</sup> monomer component should have a glass transition temperature less than approximately 30°C, preferably less than approximately 22°C. Especially useful 2<sup>nd</sup> monomer components contain n-butyl acrylate, n-hexyl acrylate, 2-ethyl hexyl acrylate, 2-ethoxy ethyl acrylate, 2,3-dibromopropyl acrylate, n-1,1-dihydroperfluorobutyl and mixtures of these.

The amount of the 3<sup>rd</sup> or crosslinking monomer component is often small compared to the amount of the 1<sup>st</sup> and 2<sup>nd</sup> monomer component. The 3<sup>rd</sup> component should make up approximately 1 wt. % or less of the co-polymer. The 3<sup>rd</sup> component of co-polymer of this invention can be regarded as a cross-linking agent. A monomer component for crosslinking is often chosen from polyfunctional components. Preferably, it can be chemically reacted with at least one functional group of the 1<sup>st</sup> monomer component and 2<sup>nd</sup> monomer component. The monomer component for crosslinking is



selected so that it can be chemically reacted to at least one functional group which is bonded to one or both of the 1<sup>st</sup> monomer component and 2<sup>nd</sup> monomer component. Examples of useful monomer components for crosslinking include ethylene glycol dimethacrylate, propylene glycol dimethacrylate, ethylene glycol diacrylate, and mixtures of these.

In especially useful examples, the co-polymer contains a 4<sup>th</sup> component which is made from a hydrophilic monomer component which is different from the 1<sup>st</sup>, 2<sup>nd</sup>, and 3<sup>rd</sup> components. This 4<sup>th</sup> component makes up at least approximately 2, or approximately 4 wt. %, and it is effective to reduce the tackiness of the co-polymer. This 4<sup>th</sup> component provides one or more desirable features. For example, compared to a practically identical co-polymer which does not contain 4<sup>th</sup> component, its tensile strength is higher, and it is more compatible with the environment in the eyes. The 4<sup>th</sup> component should make up less than approximately 15 wt. % of the co-polymer. A co-polymer which contains 15 wt. % or more of a hydrophilic monomer tends to form a hydro gel when it is exposed to water. The co-polymer of this invention should not form a hydro gel. The useful characteristics of the co-polymer of this invention are the result of selecting appropriate component rather than the formation of hydro gel from such co-polymer.

The term "hydrophilic monomer component" used in this detailed report means a compound which combines with a practical amount of hydro gel forming homo polymer, for example, at least approximately 20 % water of weight of hydro gel forming homo polymer, and then produces a homo polymer which physically swells as a result. Specific examples of useful hydrophilic monomer include N-vinyl pyrrolidone; hydroxy alkyl acrylate and hydroxy alkyl methacrylate such as 2-hydroxy ethyl acrylate, 2-hydroxy ethyl methacrylate, 3-hydroxy propyl acrylate, 3-hydroxy propyl methacrylate, 4-hydroxy butyl acrylate, 4-hydroxy butyl methacrylate, 2,3-dihydroxy propyl acrylate, 2,3-dihydroxy propyl methacrylate; N-alkyl acryl amide such as N-methyl acryl amide, N-ethyl acryl amide, N-propyl acryl amide, N-butyl acryl amide; acrylic acid; methacrylic acid, and also mixtures of these.

In one specific example, the 1<sup>st</sup> monomer component contains one or more groups containing an aryl group. Although this invention is restricted to any specific theory, the existence of groups containing aryl in the 1<sup>st</sup> monomer component is regarded to promote, induce, or acquire a higher refractive index.

If the 1<sup>st</sup> monomer component contains 1 or more group containing aryl, at least the 2<sup>nd</sup> monomer component, more preferably 2<sup>nd</sup>, 3<sup>rd</sup>, and 4<sup>th</sup> monomer component should not contain groups containing aryl groups. It was found that the refractive index of the co-polymer can be controlled effectively by controlling the specific type and amount of 1<sup>st</sup> monomer component used. In other words, the co-polymer of this invention will have the desired refractive index without requiring that the 2<sup>nd</sup> monomer component, or 2<sup>nd</sup>, 3<sup>rd</sup> and 4<sup>th</sup> monomer component have a high refractive index equivalent to the refractive index of the 1<sup>st</sup> monomer component. This "single refractive index control" is very effective for acquiring a high refractive index co-polymer. It also allows flexibility in the choice of other monomer components which can be chosen for useful characteristic other than refractive index, for example, a co-polymer for an IOL that can be deformed effectively at room temperature (for insertion).

The co-polymer of this invention can be manufactured using conventional polymerization techniques. For instance, the monomer is mixed and heated to promote the polymerization reaction. For example, a well known catalyst and/or initiator can be combined with the monomer in order to promote the polymerization reaction and/or to increase reaction speed. Examples of such initiators include 2,2'-azobis (2,4-dimethyl pentane nitrile), 2,2'-azobis (2-methyl propane nitrile), 2,2'-azobis (2-methyl butane nitrile), peroxides such as benzoyl peroxide, UV initiators such as diethoxy acetophenone, and mixtures of these. It is also possible to use an effective amount of a UV absorbing monomer component such as functional benzo triazole and benzophenone derivatives in the precursor monomer. By including such UV absorbing monomer components in the final co-polymer, the final co-polymer will have effective UV absorbing characteristics.

In one very useful example, the co-polymer of this invention is manufactured by mixing a 1<sup>st</sup> monomer component and 2<sup>nd</sup> monomer component (if any, 4<sup>th</sup> monomer component as well). This mixture is well stirred and de-gassed, and then it is heated to, for example, approximately 50 to 80 °C, and then it is kept at this temperature for 15 minutes to 3 hours. When this mixture is partially polymerized and cooled to approximately 25°C, a viscous liquid is formed.

The final co-polymer is manufactured by combining this partially polymerized viscous liquid, a monomer component for crosslinking, and a catalyst and/or initiator. It is also possible to combine or mix all the components, catalyst, and/or initiator. The viscous liquid or monomer mixture is well mixed and degassed and put into a metal mold. This metal mold is heated to preferably 40 to 100 °C approximately, and then this liquid or mixture is cured preferably for approximately 1 hour to 24 hours. Next, the substance in the metal mold is pre-cured for preferably 2 to 30 hours approximately at preferably 70 to 130 °C temperature approximately. After curing (and pre-curing), this metal mold is disassembled, and the molded optical body is removed.

Curing and pre-curing may also be done in a tube. The co-polymer formed in a tube is cut into cylindrical shaped lens blanks. These lens blanks are mechanically finished to produce a complete optical body. Such mechanical processing includes milling at extremely low temperature and lathe processing.

Referring to figure 1 and figure 2, IOL 21 includes one pair of haptic (inter-ocular lens support) or fixation parts 28 which is fixed to the optically transparent optical body 26 and extend outward in the radial direction. Each haptic 28 has a practically uniform side cut surface along its length. It also has a smooth curve 32 between the lens bond part 34 and free end part 36. The specific example shown in the figure has two opposing haptic 28. However, an IOL which has only one optically fixed haptic or three or more haptics is within the scope of this invention.

The optical body 26 is manufactured from a co-polymer of this invention, for example, the co-polymer in example of practice 1. The optical body 26 can be formed by conventional IOL formation techniques, for example, injection molding. The monomer component may be mixed and cured in a tube. The cast rod is cut into buttons, and these are processed by an extremely low temperature lathe, and an IOL optical body is formed.

In general, each haptic 28 consists of metal or a preferably flexible polymer substance, and it is practically circular in section. If desired, a different section can be

used. The haptic can be any appropriate shape. The haptic 28 shown in the figure is relatively thin and flexible. At the same time, it has sufficient strength for supporting the IOL 21 inside the eye 10. This haptic 28 can be made of various substances that show sufficient support strength and elasticity and are practically biologically inactive. Suitable substances include, for example, polymers such as polypropylene, methyl polymethacrylate, polycarbonate, polyamide, polyimide, ester polyacrylate, 2-hydroxy ester methyl methacrylate, poly(vinylidene fluoride), polytetrafluoro ethylene; metals such as stainless steel, white gold, titanium, tantalum, or a shape-memory alloy such as nitinol. The haptic can be manufactured using conventional techniques. For example, a desirable polymer haptic can be formed by conventional thermo plastic polymer formation techniques such as injection molding or extrusion.

The lens bond part 34 of the haptic 28 is fixed to optical body and it can be any shape such as a fixed loop and fixed "T", or other structures in order to provide a mechanical interlock with the optical body as done in the prior art.

The IOL 26 can be formed by using any one of various techniques that are normally used to form an IOL. For example, the lens bond part 34 of the haptic 28 can be put into a mold with the monomer component used for forming the optical body 26. Next, this metal mold is exposed to effective conditions for forming the co-polymer of this invention from this monomer, such as high temperature. The lens bonded part 34 is bonded to the optical body 26. By this, the haptic 28 is fixed to the optical body. The haptic 28 can also be fixed to preformed indentations in the optical body 26.

The refractive index of the optical body 26 is at least 1.50, and it can be bent for insertion into the eye through an approximately 3 mm incision. After it is inserted in bent condition, The IOL 21 returns to its original shape after an appropriate time, for example, in approximately 3 seconds or on the order of approximately 20 seconds to 3 minutes. Also, it can be placed in the eye easily for an effective and long lasting replacement for a natural lens.

The following examples of practice shows the embodiment of this invention, but this invention is not restricted to only these examples.

#### Example of practice 1

The following materials were mixed and purified with nitrogen gas for 3 minutes. Next, they were cured, and a crosslinking co-polymer was manufactured

| wt. % |  |
|-------|--|
| 89.6  | 2-phenoxy ethyl acrylate                   |
| 10.0  | n-hexyl acrylate                           |
| 0.35  | ethylene glycol dimethacrylate             |
| 0.05  | 2,2'-azobis (2,4-dimethyl pentane nitrile) |
| 0.05  | 2,2'-azobis (2-methyl butane nitrile)      |

The curing temperature cycle was as follows:  
 heated from 25 to 50 °C in 30 minutes;  
 maintained at 50 °C for 5 hours;  
 heated from 50 to 90 °C in 4 hours;

maintained at 90 °C for 1 hour;  
 cooled from 90 to 25 °C in 6 hours;  
 A pre-curing temperature cycle used was as follows:  
 heated from 25 to 120 °C in 3 hours;  
 maintained at 120 °C for 2 hours;  
 cooled from 120 to 25 °C in 3 hours.

The homo polymer of 2-phenoxy ethyl acrylate had a refractive index of approximately 1.56, and it was relatively hard. For example, an IOD with a diameter of 1 cm made from this homo polymer was slightly rubbery. However, when this IOD was bent into a U shape, it cracked on the bottom of the U shape. The homo polymer of n-hexyl acrylate had a glass transition temperature of 58 °C.

The acquired co-polymer had a refractive index of 1.5365. An IOD with a diameter of 1 cm was bent 180 ° without cracking, and it returned to its original shape within several seconds.

#### Example of practice 2

Using conventional techniques, an IOL was made from the co-polymer manufactured in example of practice 1 and the haptic was made from polypropylene filaments. A flat convex lens with 20 diopter and 0.305 mm edge thickness and 6.0 mm diameter had a center thickness of approximately 0.76 mm. This is an improvement compared to the same lens manufactured from a substance with a 1.46 refractive index such as silicone. When silicon with a 1.46 refractive index is used, the center thickness of the optical body was approximately 1.08 mm. This silicone optical body is hard to bend because it is relatively thick compared to the optical body manufactured from the co-polymer made in example of practice 1.

#### Example of practice 3

An IOL was manufactured like the optical body shown in example of practice 2. Two practically countering haptics manufactured from polypropylene filament as shown in figure1 and figure 2 were bonded to this optical body. This IOL was inserted into the eye through a 3 mm incision. In order to perform this insertion, the IOL was bent. When it was released in the eye, the IOL regained its original shape within 1 minute, and it was fixed in the proper position. These IOL will be effective and useful as a replacement for natural lenses.

#### Example of practice 4

The following materials was mixed and purified with nitrogen gas for 3 minutes. Next, it was cured, and a crosslinking copolymer was manufactured.

wt. %

|      |                        |
|------|------------------------|
| 89.3 | phenoxy ethyl acrylate |
| 5    | n-hexyl acrylate       |
| 5    | n-vinyl pyrrolidone    |

- 0.35 ethylene glycol dimethacrylate
- 0.05 2,2'-azobis (2,4-dimethyl pentane nitrile)
- 0.05 2,2'-azobis (2-methyl butane nitrile)
- 0.25 UV rays absorbing component <sup>(1)</sup>

<sup>(1)</sup>2-(2'-hydroxy-3.-t-butyl-5'-vinyl phenyl)-5-chloro-2H-benzotriazole

The curing and pre-curing temperature cycle was the same as in example of practice 1.

The acquired co-polymer had approximately 1.55 refractive index, and its viscosity was lower than that of the co-polymer manufactured in example of practice 1. Its tensile strength was  $762 \pm 74$  psi; breaking extension was  $143 \pm 61$  percent; modulus was  $422 \pm 70$  psi. An IOL with a diameter of 1 cm made of this co-polymer was bent  $180^\circ$  without cracking, and it returned to its original shape within several seconds.

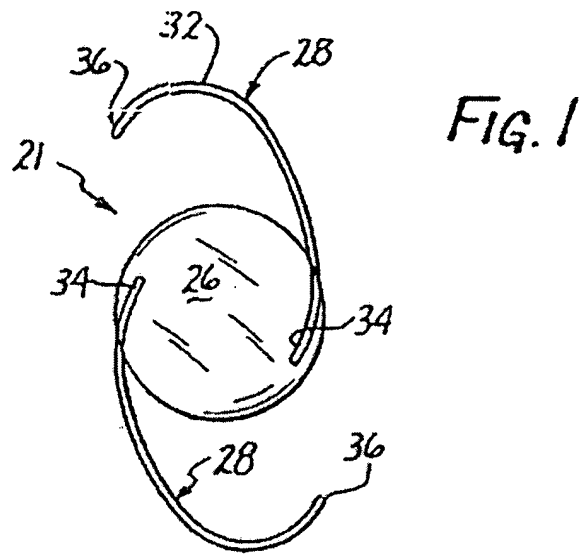
#### Example of practice 5

Using normal techniques, an IOL which contains an optical body made from the co-polymer manufactured in example of practice 4 and a haptic manufactured from polypropylene filament was formed. This IOL was practically the same shape as shown in figure 1 and figure 2.

The acquired IOL is inserted into the eye through a 3 mm incision. In order to perform the insertion, the IOL was bent. When it was released in the eye, this IOL regained its original shape within 1 minute, and it was fixed in the proper position. This IOL will be an effective and useful replacement for natural lenses.

This invention has been described using various specific examples of practice. However, this invention is not restricted only these examples. It should be understood that it can be practiced in various ways within the range of the examples of practice.

【図 1】



【図 2】

